APPLICANT DETAILS

APPLICANT DETAILS

Q1 Applicant Full name | Title

Contact address

Tel | Fax

Email

Q2 Title of Proposal

Q3 Proposed start date (dd/mm/yyyy)

Q4 Department name and address of administering organisation where different from applicant's contact address:

Q5 Applicant

Personal Details	
Full name	
Title (Dr, Prof etc.)	
Present post	
Telephone number	
Fax number	
E-mail address	

Applicant contract of employment

With whom do you have your contract of employment?

Expected date of termination of contract of employment: (dd/mm/yyyy)

Source of personal salary support (If 'Other', please specify):
Please also be specific if salary is funded from more than one source.

Q5 Co-Applicant

Personal Details	
Full name	
Title (Dr, Prof etc.)	
Present post	
Telephone number	
Fax number	
E-mail address	

With whom do you have your contract of employment?

Expected date of termination of contract of employment:
(dd/mm/yyyy)

Source of personal salary support (If 'Other', please specify):
Please also be specific if salary is funded from more than one source.

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Q12 LAY SUMMARY

Please provide a summary of your proposed research, including key goals, for a non-expert audience (no more than 200 words)

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Q13 DETAILS OF RESEARCH PROJECT

Detail (a) Aims of the project. (b) Work which has led up to the project. (c) Approach and methods to be used. (d) Contingency plans. (e) Timetable and milestones, if appropriate. **For clinical trials, refer to guidelines**.

No more than **700** words should be used to describe the research project.

REFERENCES (Research project)

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Q14 CLINICAL TRIAL DETAILS

Does your proposal involve a clinical trial? Yes/No

What are the proposed participating centres and the roles of the clinical trial team members? Provide details of any activity to be undertaken by a third party and comment on the plans to ensure the presence of a formal contract. (200 words max.)

Please describe the study design including planned interventions (experimental and control), duration of treatment, and any potential significant risks to participants. Details of any investigational product should be provided with particular regard to manufacture, quality and consistence (300 words max.)

Describe the inclusion/exclusion criteria. What are the proposed methods for protecting against source of bias? What are the proposed arrangements for allocating participants to the trial groups? (200 words max.)

What are the envisaged primary and secondary outcome measures, and how will these be assessed at follow up? Describe the proposed frequency and duration of follow up and any anticipated problems with non-compliance and/or loss to follow up. (200 words max.)

Detail and justify the sample size and proposed statistical analysis including any interim analyses and/or subgroup analyses. Outline and justify the strategy for recruitment (200 words max.)

How have patients, patient advocacy groups or communities been involved in developing the clinical aspects of this proposal? (300 words max.)

Describe anticipated regulatory and governance approvals, and the proposed arrangements for trial management. What is the proposed membership of the Trial Steering Committee and the Data Monitoring and Ethics Committees? (200 words max.)

Q15 DATA MANAGEMENT & DATA SHARING

(a) Will the proposed research generate data outputs that hold significant value as a resource for the wider research community?

(b) If yes, please provide a Data Management and Sharing Plan below (no more than 2000 words)

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Q16 DETAILS OF FINANCIAL SUPPORT REQUESTED

IS MATCH FUNDING AVAILABLE? YES/NO (IF YES PLEASE STATE DETAILS)

IS ANY OTHER FUNDING AVAILABLE? YES/N0 (IF YES PLEASE STATE DETAILS)

IS THE AMOUNT REQUIRED FOR ALL THE PROJECT OR IS THE PROJECT RECEIVING FUNDING FROM OTHER AREAS? (PLEASE STATE)

Who is the host institution? Please add contact information

Do you need ethical approval? If so the foundation must receive evidence ethical approval is in place prior to the project starting. It is the responsibility of the grantee you make due application of ethical approval and this should ideally be in place at the time of applying for funding. Any payments will be delayed until evidence is provided.

COST OF PROJECT AND BREAKDOWN - CAN YOU PROVIDE INFORMATION ON FUNDING STRUCTURE AND FUNDING REQUIREMENTS AND PAYMENTS

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ANIMALS

Are you requesting animals?

Total purchase cost Total maintenance cost Total procedures cost	
Total	

The table below should be duplicated for **each different species.**

(1)	**Animal species to be used, and strain if relevant**	
(2)	**Source of supply**	
(3)	**Purchase**	
	Purchase price per animal	
	Total number of animals to be purchased	
	Total purchase cost	
(4)	**Maintenance**	
	Total number of animals to be maintained	
	Total number of weeks' maintenance required	
	Cost per animal per week	
	Total maintenance cost	
(5)	**Experimental procedures**	
	Types of procedure(s)	
	Cost per procedure(s)	
	Total procedures cost	

The table below should be duplicated for **each different species.**

(1)	**Animal species to be used, and strain if relevant**	
(2)	**Source of supply**	
(3)	**Purchase**	
	Purchase price per animal	
	Total number of animals to be purchased	
	Total purchase cost	

(4)	**Maintenance**	
	Total number of animals to be maintained	
	Total number of weeks' maintenance required	
	Cost per animal per week	
	Total maintenance cost	
(5)	**Experimental procedures**	
	Types of procedure(s)	
	Cost per procedure(s)	
	Total procedures cost	

JUSTIFICATION OF ANIMALS REQUESTED

In this section, justify:

Animals (sample size and species) (no more than 500 words). Please give evidence or calculations for experimental group sizes and describe any plans to reduce bias (eg. blinding, randomisation).

Q17 RESEARCH INVOLVING HUMAN PARTICIPANTS, BIOLOGICAL SAMPLES AND PERSONAL DATA RELATING TO LIVING OR DEAD PERSONS

(a) Does your project involve human participants, human biological material or identifiable/potentially identifiable data?
If yes, refer to notes.

(b) If yes, please confirm that you have read the guidance on the feedback of health-related findings in research and are in the process of considering your approach to this.

Please state:

By whom and when the ethics of the project has been reviewed, and specify any other regulatory approvals that have been obtained.

And/or:

(ii) By whom and when the ethics of the project will be reviewed, and specify any other regulatory approvals that will be sought.

(e) In the course of your project:

(i) Do you propose to use facilities within the National Health Service (NHS)?

(ii) Does your research involve patients being cared for by the NHS?

(iii) If the answer is yes to (i) or (ii) above, please indicate which organisation has agreed to be the sponsor for the project under the Research Governance Framework for Health and Social Care, published by the Department of Health in England or the corresponding departments in Northern Ireland, Scotland or Wales.
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(f) Does your project involve a clinical trial?
If yes, refer to notes and submit the requested information.

(g) If your project involves a clinical trial:

(i) Is a formal sponsor required for the project, eg under the Medicines for Human Use (Clinical Trials) Regulations or the Research Governance Framework for Health and Social Care and equivalent guidance?

(ii) Please indicate which organisation has agreed to be the sponsor for the project.

(iii) Please confirm that
(1) an independent Trial Steering Committee (TSC) will be established (If any other type of independent monitor is to be implemented, please indicate and provide any relevant details)

(2) approval will be obtained for the trial protocol, typically by the TSC, prior to commencement of the trial

(3) the trial will be registered on the International Standard Randomised Controlled Trial Number Register (ISRCTN), ClinicalTrials.gov, or on another register listed on the WHO International Clinical Trials Registry Platform (ICTRP)

(h) If any potentially commercially exploitable results may be based upon tissues or samples derived from human participants, please confirm that there has been appropriate informed consent for such use.

Q18 EXPERIMENTS ON ANIMALS

(a) Do your proposals involve the use of animals?

(b) Do your proposals involve the use of animal tissue?

(c) Do your proposals include procedures to be carried out on animals in the UK which require a Home Office licence?
If yes, refer to notes.

(d) Does the organisation where the animal work is to be carried out hold a certificate of designation under the Animals (Scientific Procedures) Act 1986?

(e) Do your proposals involve the use of animals or animal tissue outside the UK?
If yes, refer to notes.

(f) If your project does involve the use of animals, what would be the severity of the procedures? Please choose between 'Mild', 'Moderate' and 'Substantial'.

(g) Please provide details of any procedures of substantial or moderate severity (no more than 250 words).

(h) Why is animal use necessary: are there any other possible approaches? (no more than 250 words)

(i) Why is the species to be used the most appropriate? (no more than 250 words)

Q19 RISKS OF RESEARCH MISUSE

(a) It is the responsibility of organisations in receipt of funding to ensure that any risks that research could be misused for harmful purposes are managed in an appropriate manner.

Please confirm that you have considered whether your proposed research could generate outcomes that could be misused for harmful purposes.

(b) Have you identified any tangible risks of this type?

(c) If you have identified any tangible risks of this type, please briefly describe these risks and the steps that you and your organisation will take to manage them (no more than 250 words).

Q20 FREEDOM TO OPERATE/CONFLICTS OF INTEREST

Do any of the applicants have consultancies or any equity holdings in, or directorships of, companies or other organisations that might have an interest in the results of the proposed research?

Will the proposed research use technology, materials or other invention that, as far as you are aware, are subject to any patents or other form of intellectual property protection?

Is the proposed research, in whole or in part, subject to any agreements with commercial, academic or other organisations?

If yes, refer to notes and give brief details (no more than 350 words).

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